

Application Number 10/723,316  
Amendment responsive to Office Action mailed May 9, 2007

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### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

#### Listing of Claims:

Claim 1 (Currently Amended): A method for treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatic pain and prostatic dysfunction in a patient, comprising:

~~providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to treat at least partially at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatic pain and prostatic dysfunction in the patient;~~

~~providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacrotuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;~~

~~implanting a distal end of the a first implantable medical electrical lead in tissue of the patient adjacent, around or in one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacrotuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, wherein the first lead comprises at least a first electrode;~~

~~operably connecting the a proximal end of the at least first lead to the an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime via at least the first lead;~~

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implanting the implantable pulse generator within the patient; and

delivering electrical stimulation pulses from the implantable pulse generator to ~~at least a portion of the tissue of the patient~~ one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacrotuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and ~~providing to the patient~~ delivered in a configuration effective to provide at least partial relief from at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostaticgia and prostatodynia.

Claim 2 (Cancelled).

Claim 3 (Previously Presented): The method of claim 1, wherein the at least first lead comprises a beam steering lead comprising multiple electrodes.

Claim 4 (Previously Presented): The method of claim 1, wherein the at least first lead comprise an active fixation device or member disposed thereon, attached thereto or forming a portion thereof.

Claim 5 (Previously Presented): The method of claim 1, wherein the at least first lead includes a fixation device or member selected from the group consisting of a suture sleeve, a barb, a helical screw, a hook and a tissue in-growth mechanism.

Claim 6 (Cancelled).

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**Claim 7 (Currently Amended):** The method of claim 1, further comprising providing, implanting, operably connecting and delivering electrical stimuli from a second implantable medical electrical lead ~~configured for implantation adjacent, around or in at least one of a sacral nerve or branches or portions thereof, a pudendal nerve or branches or portions thereof, a hypogastric nerve or branches or portions thereof, or a prostatic plexus nerve or branches or portions thereof of the patient,~~ wherein the second lead comprises proximal and distal ends and at least one electrode.

**Claim 8 (Original):** The method of claim 7, further comprising delivering the electrical pulses through tissue disposed between the electrodes located on the first and second leads.

**Claim 9 (Currently Amended):** The method of claim 1, wherein the electrical stimulation pulses that are delivered to ~~the desired nerve target sites or portions~~ one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberos ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion located in the vicinity of the at least one electrode.

**Claim 10 (Original):** The method of claim 1, further comprising providing a lead extension, operably connecting same between the proximal end of the at least first lead and the implantable pulse generator, and delivering the electrical stimulation pulses through the lead extension.

**Claim 11 (Previously Presented):** The method of claim 1, wherein the first lead comprises at least one electrode selected from the group consisting of an electrode formed from a portion of wire, a barb or a hook, a spherically-shaped electrode, and a helically-shaped electrode.

**Claims 12-13 (Cancelled).**

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**Claim 14 (Previously Presented):** The method of claim 1, wherein the distance between the proximal and distal ends of the at least first lead is selected from the group consisting of about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches.

**Claims 15-19 (Cancelled).**

**Claim 20 (Previously Presented):** The method of claim 1, wherein the implantable pulse generator and the at least first lead are capable of generating and delivering electrical pulses having frequencies ranging between about 50 Hz and about 100 Hz, between about 10 Hz and about 250 Hz, or between about 0.5 Hz and about 500 Hz.

**Claim 21 (Previously Presented):** The method of claim 1, wherein the implantable pulse generator and the at least first lead are capable of generating and delivering electrical pulses having amplitudes ranging between about 1 Volt and about 10 Volts, between about 0.5 Volts and about 20 Volts, or between about 0.1 Volts and about 50 Volts.

**Claim 22 (Previously Presented):** The method of claim 1, wherein the implantable pulse generator and the at least first lead are capable of generating and delivering electrical pulses having pulse widths ranging between about 180 microseconds and about 450 microseconds, between about 100 microseconds and about 1000 microseconds, or between about 10 microseconds and about 5000 microseconds.

**Claim 23 (Currently Amended):** The method of claim 1, wherein delivering first electrical stimulation pulses comprises:

generating a plurality of different electrical signals, electrical pulses of the electrical signals having respective spatial or temporal phases for respective delivery to the first lead and at least a second lead; and

delivering the pulses to ~~at least portions of the tissue of the patient~~ one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the

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scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof.

Claim 24 (Previously Presented): The method of claim 1, wherein the electrical stimulation pulse regime provided to the patient is effective in providing at least one of urinary urgency relief or urinary frequency relief.

Claim 25 (Original): The method of claim 1, wherein the electrical stimulation pulse regime provided to the patient is effective in providing relief from sexual dysfunction.

Claim 26 (Previously Presented): The method of claim 1, further comprising concomitantly delivering a drug to the patient and delivering the electrical stimulation regime.

Claim 27 (Previously Presented): The method of claim 26, further comprising providing, implanting and activating an implantable drug pump for providing the drug to the patient.

Claim 28 (Currently Amended): A method for treating urinary retention disorder in a patient comprising:

~~providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to treat at least partially urinary retention disorder in the patient;~~

~~providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of a pudendal nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof, a sacral splanchnic nerve or branches or portions thereof, a pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or~~

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~~branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;~~

implanting a distal end of the a first implantable medical electrical lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, wherein the first lead comprises at least a first electrode;

operably connecting the a proximal end of the at least first lead to the an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime via at least the first lead;

implanting the implantable pulse generator within the patient; and

delivering electrical stimulation pulses from the implantable pulse generator to at least a portion of the tissue of the patient one of the pudendal nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof,

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scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and providing to the patient delivered in a configuration effective to provide at least partial relief from urinary retention disorder.

Claim 29 (Currently Amended): The method of claim 28,

~~wherein providing at least a first implantable medical electrical lead comprises providing the first implantable medical electrical lead configured for implantation adjacent, around or in at least one of the pudendal nerve or branches or portions thereof, and~~

wherein implanting the first lead comprises implanting the first lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof.

Claim 30 (Currently Amended): A method for treating at least one of prostatitis, prostatic pain or prostatic dysfunction in a patient, comprising:

~~providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to treat at least partially at least one of prostatitis, prostatic pain or prostatic dysfunction in the patient;~~

~~providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;~~

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implanting a distal end of the a first implantable medical electrical lead in tissue of the patient adjacent, around or in one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, wherein the first lead comprises at least a first electrode;

operably connecting ~~the a~~ proximal end of the at least first lead to ~~the an~~ hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime via at least the first lead;

implanting the implantable pulse generator within the patient; and

delivering electrical stimulation pulses from the implantable pulse generator to ~~at least a portion of the tissue of the patient~~ one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and ~~providing to the patient~~ delivered in a configuration effective to provide at least partial relief from at least one of prostatitis, prostaticgia or prostatodynia,

wherein the electrical stimulation pulses that are delivered to ~~the desired nerve target sites or portions~~ one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal



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nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion located in the vicinity of the at least one electrode.

Claims 31-32 (Cancelled).

**Claim 33 (Previously Presented):** The method of claim 30, wherein implanting the first lead comprises:

delivering stimulation to a plurality of locations via a St. Mark's electrode, the locations comprising one or more of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof;

sensing an evoked response for each of the locations;

selecting one of the locations based on the evoked responses; and

implanting electrodes of the first lead adjacent, around, or in tissue at the selected location.

**Claim 34 (Previously Presented):** The method of claim 33, wherein sensing an evoked response comprises sensing an anal or vaginal electromyogram for each of the locations.

**Claim 35 (Previously Presented):** The method of claim 34, further comprising determining a latency of the electromyogram for each location, wherein selecting one of the locations comprises selecting the location based on the latency.

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**Claim 36 (Previously Presented):** A method for treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatic pain and prostaticodynia in a patient, comprising:

delivering stimulation to a plurality of locations via a St. Mark's electrode, the locations comprising one or more of the sacral nerve or branches or portions thereof, the pudendal nerve or branches or portions thereof, the hypogastric nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof;

sensing an evoked response for each of the locations;

selecting one of the locations based on the evoked responses;

implanting electrodes of the first implantable medical electrical lead in tissue of the patient adjacent, around or in the selected location; and

delivering electrical stimulation pulses from an implantable electrical pulse generator to at least a portion of the tissue of the patient through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and providing to the patient at least partial relief from at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatic pain and prostaticodynia.

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Claim 37 (Previously Presented): The method of claim 36, wherein sensing an evoked response comprises sensing an anal or vaginal electromyogram for each of the locations.

Claim 38 (Previously Presented): The method of claim 37, further comprising determining a latency of the electromyogram for each location, wherein selecting one of the locations comprises selecting the location based on the latency.

Claim 39 (Currently Amended): A method for treating pelvic pain comprising:

~~providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to at least partially treat pelvic pain in the patient;~~

~~providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;~~

~~implanting the a distal end of at least a first medical electrical lead in tissue of the patient adjacent, around or in at least one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, or the sacro-tuberous ligament or branches or portions thereof, wherein the first lead comprises at least a first electrode;~~

~~operably connecting the a proximal end of the at least first lead to the an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime via at least the first lead;~~

~~implanting the implantable pulse generator within the patient; and~~

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delivering electrical stimulation pulses from the implantable pulse generator to at least a ~~portion of the tissue of the patient~~ one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, or the sacro-tuberous ligament or branches or portions thereof through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and ~~providing to~~ in a configuration effective to provide the patient at least partial relief from pelvic pain,

wherein the electrical stimulation pulses that are delivered to the desired nerve target sites or portions cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion located in the vicinity of the at least one electrode.